UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

Anastasia Johnston, individually and on behalf of Claire Johnston, Claire Johnston, Karl Thomsen, Debra Bailey, Laura Chapin, individually and on behalf of minor Fionn Chapin, and Rachel Fernandez, individually and on behalf of minor Hope Moran, on behalf of themselves and all others similarly situated, Plaintiffs, v Mylan Specialty L.P. and Mylan Pharmaceuticals Inc., Defendants.	Case No. Hon. CLASS ACTION JURY TRIAL DEMAND

CLASS ACTION COMPLAINT AND JURY DEMAND

Plaintiffs Anastasia Johnston, individually and on behalf of Claire Johnston, Claire Johnston, Karl Thomsen, Debra Bailey, Laura Chapin, individually and on behalf of minor Fionn Chapin, and Rachel Fernandez, individually and on behalf of minor Hope Moran, by their undersigned attorneys, bring this complaint against defendants Mylan Specialty L.P., formerly known as Dey Pharma, and Mylan Pharmaceuticals Inc. ("Defendants"). Plaintiffs' allegations are based upon

information and belief. Plaintiffs' information and belief are based upon, among other things, an extensive investigation undertaken by their attorneys.

Overview

1. This case seeks redress for Defendants' deceptive and unconscionable practice of requiring that EpiPens be sold in sets of two as a pretense for charging unconscionable prices to class members who rely on EpiPens for protection of their life and health. In short, Defendants are misstating the science of EpiPen dosage in order to purportedly justify its price gouging.

The Parties

2. Plaintiff Anastasia Johnston, individually and on behalf of Claire Johnston, is a resident of Oakland County, Michigan.

3. Plaintiff Claire Johnston is a resident of Oakland County, Michigan.

4. Plaintiff Karl Thomsen is a resident of Traverse City, Michigan.

5. Plaintiff Debra Bailey is a resident of Viper, Kentucky.

6. Plaintiff Rachel Fernandez, individually and on behalf of minor Hope Moran, is a resident of Milford, Connecticut.

7. Plaintiff Laura Chapin, individually and on behalf of minor Fionn Chapin, is a resident of Berlin, New Hampshire.

8. Defendant Mylan Pharmaceuticals Inc. ("Mylan") is a corporation organized under the laws of West Virginia with its headquarters in Canonsburg, Pennsylvania.

9. Defendant Mylan Specialty L.P., formerly known as Dey Pharma, is a limited partnership organized under the laws of Delaware with its headquarters in Basking Ridge, New Jersey (hereinafter, "Dey"). Dey is a wholly owned subsidiary of Mylan.

Jurisdiction and Venue

10. The Court has jurisdiction over this matter pursuant to 28 U.S.C. 1332(d), in that this is a class action in which the matter or controversy exceeds the sum of $5,000,000, exclusive of interest and costs, and in which some members of the proposed Class are citizens of a state different from Defendants.

11. This Court has personal jurisdiction over Defendants because Defendants continually and systematically transact business within the State of Michigan.

12. Venue is proper in the Eastern District of Michigan under 28 U.S.C. 1391(b) and (c) and 15 U.S.C. §§ 15 and 22 because: (a) Defendants transact business and/or committed an illegal or tortious act in this District; and (b) a substantial portion of the affected interstate trade and commerce described below has been carried out in this District.

Common Allegations

13. Epinephrine, also known as adrenaline, is a medication and hormone that is used for emergency treatment of severe allergic reactions (including anaphylaxis) caused by insect bites or stings, medicines, foods, or other substances. Epinephrine is also used to treat anaphylaxis that is caused by unknown substances or triggered by exercise. It is only available by prescription.

14. Anaphylaxis is a life-threatening reaction, and it requires immediate medical attention. Even if a patient feels better after using epinephrine, they should go to an emergency room or check with their doctor as soon as possible.

15. The EpiPen is a type of epinephrine injection device, or autoinjector. While using an epinephrine autoinjector, the patient injects the epinephrine into the muscle of their outer thigh through the device's spring-loaded needle. Patients are advised to carry the medication with them at all times for emergency use if they are at risk of having a severe allergic reaction.

16. EpiPen was approved by the United States Food and Drug Administration on December 22, 1987 under New Drug Application 019430.

17. Epinephrine comes in an autoinjector syringe and needle kit that contains the prescribed amount. Epinephrine has a limited shelf-life. Patients are advised not to keep outdated medicine or medicine that is no longer needed. They

should store the injection kits at room temperature, away from heat, moisture, and direct light.

18. Dey has worldwide rights to EpiPen auto injector. A wholly owned subsidiary of Pfizer provides the auto injectors to Dey.

19. Dey was acquired by Mylan in 2007 from Merck.

20. At the time Dey changed to the two pack, EpiPen was the number one prescribed epinephrine auto-injector with 95% of the United States market and 90% of the worldwide market.

21. Since acquiring Dey in 2007, Mylan has increased the wholesale price of EpiPen approximately 400%.

22. In December 2010, the National Institute of Allergy and Infectious Diseases ("NIAID"), a division of the National Institutes of Health, introduced the "Guidelines for the Diagnosis and Management of Food Allergy in the United States." Several members of the expert committee had received funding from Dey Pharmaceuticals in the past. These guidelines state that epinephrine is the first line treatment for anaphylaxis.

23. The NIAID report provided limited information concerning the possible need for additional doses of epinephrine during a serious anaphylactic reaction.

24. At the time the NIAID report was released, doctors had the freedom to choose whether to prescribe single EpiPens or two packs.

25. Nonetheless, the EpiPen subsequently became available only in two-pack cartons. According to Mylan, "This follows National Food Allergy Guidelines that recommend people at increased risk for anaphylaxis have two doses of epinephrine available at all times." Mylan explains that there could be either a protracted reaction or a biphasic reaction, which could make a second dose necessary (more than two doses should not be self-administered or administered without direct medical supervision).

26. Specifically, on August 24, 2011, Dey issued a press release concerning the NIAID report pointing out that they would no longer be offering EpiPen in a single pack. In the press release Mylan's President Heather Bresch was quoted:

> "Many people may not be aware that recent food allergy guidelines state that patients at risk for or who have experienced anaphylaxis should have immediate access to two doses of epinephrine. The decision to exclusively offer the EpiPen 2-Pak, which contains two single EpiPen Auto-Injectors, aligns with these guidelines, as well as with the 2011 World Allergy Organization (WAO) anaphylaxis guidelines which recommend that physicians consider prescribing more than one epinephrine auto-injector. (Citation omitted). Mylan and Dey are committed to increasing the overall awareness of being prepared for a potentially life-threatening allergic reaction."

27. The press release then goes on to quote Dr. Phillip Lieberman, Clinical Professor of Medicine and Pediatrics at University of Tennessee College of Medicine who was a member of the NIAID expert panel.

> Dr. Phillip Lieberman, Clinical Professor of Medicine and Pediatrics at University of Tennessee College of Medicine, and member of the NIAID-sponsored expert panel added: "The guidelines recognize that up to 20% of those who receive epinephrine will require more than one dose before symptoms are relieved. In addition, the need for additional epinephrine cannot be reliably predicted at the onset of a reaction. (Citation omitted). Therefore, consistent with the guidelines, patients prescribed an epinephrine auto-injector should be given a prescription which allows two doses."

28. In fact, though, Mylan did not follow the advice of the NIAID. Instead of giving doctors the option to prescribe one or more EpiPens, Mylan forced doctors to prescribe EpiPens in two packs. This is also inconsistent with the NIAID report that *recommended* but did not require prescriptions for two EpiPens, and only for patient specific circumstances.

29. The press release also contained the following statement:

> Dey is no longer shipping single EpiPen Auto-Injector package configurations in the U.S.; however, the single EpiPen Auto-Injector may still be available at certain pharmacies for a few weeks until their stock is depleted. The single EpiPen Auto-Injector package configuration will continue to be available outside of the U.S.

30. This statement demonstrates that Mylan's actions had little, if anything to do with patient safety. The fact that the single EpiPen packages will be

available outside the U.S. shows that Mylan was improperly taking advantage of U.S. patients. If patient safety was the paramount concern, then Mylan would have stopped production of single EpiPens worldwide.

31. There is minimal evidence that providing a second EpiPen for use during a severe anaphylaxis event provides a benefit to patients. One of the key studies relied upon by Defendants as justification for requiring the two pack shows that only a small percentage of individuals required a second dose of epinephrine. Furthermore, of those requiring a second dose, all but one received their second dose from a health care professional. Lastly, the need for two packs in adults has not been reliably studied to show that there is any significant benefit as opposed to allowing doctors to make choices concerning whether to prescribe a single EpiPen or multiple EpiPens.

32. By offering EpiPens in a dual pack, Mylan has taken away the judgment of physicians.

33. Furthermore, in the event that an individual uses one EpiPen, they have no choice but to replace it with two EpiPens. This results in forced purchases of additional EpiPens—which are wasteful to patients but a windfall for Defendants. Mylan ignores the most critical directive—for patients to seek immediate emergency care.

34. The market for epinephrine autoinjectors is large, and it is dominated by Mylan's EpiPen. The epinephrine autoinjector market is now worth a reported $1.3 billion, and Mylan holds an 85% market share with its EpiPen. The market has grown substantially in recent years, largely due to Mylan's marketing, branding, and public awareness campaigns. From 2007 to 2014, the price of the EpiPen rose by 222% and the EpiPen generated $200 million in revenue as recently as 2007. Mylan's market share was 96% in the U.S. in 2009.

35. Because doctors were well aware that they might need to prescribe multiple EpiPens, there was no legitimate need to eliminate the single EpiPen from a patient safety perspective. Using the 2010 NIAID report as an excuse to only provide dual packs has misled the American public.

36. In short, Defendants have misstated the science regarding, and regulatory framework governing, EpiPens in order to require consumers to buy extra, unneeded EpiPens, which are likely to go to waste, at an inflated cost.

37. Each of the Plaintiffs purchased a two pack of EpiPens for their own protection or that of a friend or family member.

Class Action Allegations

38. This is a class action which seeks to: (1) enjoin Defendants' violations of state consumer protection statutes and common law; and (2) award any and all relief and damages available for Defendants' wrongful acts.

39. Plaintiffs bring this action pursuant to Fed. R. Civ. P. 23(a) and 23(b)(2) and (b)(3) on behalf of themselves and on behalf of all other similarly situated individuals and seek to represent the following class (and subclasses):

(a) All purchasers of EpiPens who were required to buy two packs of EpiPens or who would in the future be required to do so in the absence of the relief requested in this action (the "National Class");

(b) All purchasers of EpiPens who were required to buy two packs of EpiPens or who would in the future be required to do so in the absence of the relief requested in this action who resided or reside at the time of Epipens' purchase in Michigan (the "Michigan Subclass");

(c) All purchasers of EpiPens who were required to buy two packs of EpiPens or who would in the future be required to do so in the absence of the relief requested in this action who resided or reside at the time of EpiPens purchase in Kentucky (the "Kentucky Subclass");

(d) All purchasers of EpiPens who were required to buy two packs of EpiPens or who would in the future be required to do so in the absence of the relief requested in this action who resided or reside at the time of EpiPens purchase in Connecticut (the "Connecticit Subclass"); and

(e) All purchasers of EpiPens who were required to buy two packs of EpiPens or who would in the future be required to do so in the absence of the relief requested in this action who resided or reside at the time of EpiPens' purchase in New Hampshire (the "New Hampshire Subclass");.

40. The Class Period is defined as the time period applicable under the claims to be certified.

41. Excluded from the Class are Defendants, their assigns, successors, legal representatives, and any entities in which Defendants have a controlling interest.

42. Plaintiffs reserve the right to revise these class definitions and to add additional subclasses as appropriate based on facts learned as the litigation progresses.

43. **Numerosity:** The Class is sufficiently numerous that joinder of all members is impracticable. The exact number and addresses of the members of the proposed Class is unknown and is not available to Plaintiffs at this time, however, the market size and market penetration figures cited above indicate a large number of EpiPens purchasers affected by the conduct alleged herein.

44. **Commonality:** Numerous questions of law and fact are common to the claims of Plaintiffs and the members of the proposed Class. These include, but are not limited to, whether:

a. Defendants unconscionably inflated the price of EpiPens;

b. Defendants unconscionably misled consumers as to the effectiveness of single-dose EpiPens;

c. Defendants fail to disclose the possible effectiveness of single-dose EpiPens;

d. Defendants used the purported need for double-dose EpiPens as a pretense to unconscionably raise the price of EpiPens;

e. Defendants violated the consumer protection statutes applicable to each subclass;

f. Defendants are being unjustly enriched by engaging in the acts and practices alleged herein;

g. Plaintiffs and members of the Class have been and continue to be damaged by Defendants' alleged misconduct and, if so, the proper measure of their damages; and

h. Defendants engage in practices that warrant equitable and injunctive relief.

45. **Typicality:** Plaintiffs' claims are typical of the claims of all members of the proposed Class. Plaintiffs and all members of the proposed Class were damaged by the same wrongful conduct of Defendants as alleged herein and the relief sought is common to the proposed Class. The claims of Plaintiffs and all other members of the proposed Class arise out of the same alleged unlawful conduct.

46. **Adequacy of Representation:** Plaintiffs are committed to the vigorous prosecution of this action. Plaintiffs will fairly and adequately protect the interests of the members of the proposed Class, and Plaintiffs' interests are

coincident with and not antagonistic to the other members of the proposed Class who they seek to represent. Plaintiffs have retained counsel competent and experienced in class action, consumer protection, and other complex litigation.

47. **Predominance and Superiority:** Questions of law common to the members of the Class predominate over any questions affecting only individual members with respect to some or all issues presented in this Complaint. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Individual litigation of the claims of all members of the Class is impracticable because the cost of litigation would be prohibitively expensive for each member of the Class and would impose an immense burden upon the courts. However cumulatively, the amount of potential damage is significant and injunctive relief is required to preclude the Defendants' ongoing wrongful conduct.

48. **Prevention of Inconsistent or Varying Adjudications:** Individualized litigation would also present the potential for varying, inconsistent, or contradictory judgments and would magnify the delay and expense to all parties and to the court system resulting from multiple trials of the same complex factual and legal issues. By contrast, the conduct of this action as a class action, with respect to some or all of the issues presented in this Complaint, presents fewer management difficulties, conserves the resources of the parties and of the court system, and is the only means to protect the rights of all members of the Class.

49. Defendants have acted and will act on grounds generally applicable to the Class as a whole, and Plaintiffs seek, *inter alia*, equitable remedies including final injunctive relief with respect to the Class as a whole.

50. The likelihood that individual members of the Class will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Plaintiffs are not likely to be able to vindicate and enforce their rights unless this action is maintained as a class action.

51. Plaintiffs' counsel, who are highly experienced in class actions, foresee little difficulty in the management of this case as a class action.

COUNT I
Violation of State Deceptive and Unfair Trade Practice Acts and/or Consumer Protection Acts

50. Plaintiffs incorporate by reference each and every preceding allegation as if it is specifically set forth herein.

51. Defendants engaged in commercial conduct by selling the EpiPens and placing them into the stream of commerce.

52. Defendants made misstatements regarding the EpiPens by suggesting that two were required for effectiveness and that this requirement was the reason they were selling the two packs only; omitted material information concerning the EpiPens, such as their effectiveness in single doses and the reason for the two pack requirements; and engaged in unconscionable, unfair, and/or deceptive acts by

requiring consumers to buy the EpiPens as two packs. These deceptive and/or misleading representations regarding EpiPens would have deceived an objectively reasonable person.

53. Defendants' unfair practices offend public policy and are immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers.

54. Plaintiffs and members of the Class would not have purchased the two packs had they been fully informed regarding the above-referenced policies and procedures, or only would have done so in light of the risk to their health from avoiding such purchase.

55. Defendants profited from the two pack requirement for EpiPens, which was a thinly veiled mechanism for increasing their price.

56. Defendants' concealment of material facts, including the effectiveness of single EpiPens doses and the actual reason for the two pack requirement, constitutes unconscionable commercial practices, deception, false pretenses, the knowing concealment, suppression, or omissions of material facts with the intent that others would rely on such concealment, suppression, or omission in connection with the sale of the EpiPens under the substantially similar Consumer Protection laws of all other states in which Defendants do business.

57. State legislatures generally enact Unfair Trade and Deceptive Practices Acts and/or Consumer Protection Acts to protect consumers from

deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by falsely representing that two doses of EpiPens were required in order to purportedly justify the Double Pack requirement and attendant price increase.

58. Defendants' acts violate the applicable Unfair Trade and Deceptive Practices Acts and/or Consumer Protection Acts of all States where Defendants do business.

59. Defendants' acts rise to the level of intentional, willful, and wanton misconduct and/or gross negligence.

60. As a direct and proximate result of Defendants' acts and violations of the applicable Unfair Trade and Deceptive Practices Acts and/or Consumer Protection Acts of all States where Defendants do business, Plaintiffs and members of the Class have suffered actual damages.

61. Plaintiffs and members of the Class are entitled to recover statutory penalties, actual, consequential, and punitive damages, equitable and declaratory relief, costs and reasonable attorneys' fees.

COUNT II
Kentucky Consumer Protection Act, KRS §§ 367.110 *et seq.*
(On Behalf of the Kentucky Subclass)

62. Plaintiffs repeat and reallege each and every allegation set forth above as if fully set forth herein.

63. The Kentucky Consumer Protection Act prohibits "[u]nfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce." Ky. Rev. Stat. Ann. 367.170.

64. Plaintiff Debra Bailey and members of the Kentucky Subclass purchased "goods or services primarily for personal, family or household purposes" as alleged herein.

65. Defendants engaged in unfair, false, misleading, or deceptive acts or practices through the unlawful conduct alleged herein.

66. As a result of Defendants' unfair, false, misleading, or deceptive acts or practices alleged herein, Plaintiff Debra Bailey and the members of the Kentucky Subclass have suffered damages and an ascertainable loss of money or property in an amount to be determined at trial.

67. Plaintiff Debra Bailey and members of the Class are entitled to recover statutory penalties, actual, consequential, and punitive damages, equitable and declaratory relief, costs and reasonable attorneys' fees.

COUNT III
Michigan Consumer Protection Act, MCL § 445.901 *et seq.*
(On Behalf of the Michigan Subclass)

68. Plaintiffs repeat and reallege each and every allegation set forth above as if fully set forth herein.

69. The Michigan Consumer Protection Act prohibits "Unfair, unconscionable, or deceptive methods, acts, or practices in the conduct of trade or commerce." MCL § 445.903.

70. Plaintiffs Anastasia Johnston, individually and on behalf of Claire Johnston, Claire Johnston, and Karl Thomsen and members of the Michigan Subclass purchased "goods or services primarily for personal, family or household purposes" as alleged herein.

71. Defendants engaged in unfair, false, misleading, or deceptive acts or practices through the unlawful conduct alleged herein.

72. As a result of Defendants' unfair, false, misleading, or deceptive acts or practices alleged herein, Plaintiffs Anastasia Johnston, individually and on behalf of Claire Johnston, Claire Johnston, and Karl Thomsen and the members of the Michigan Subclass have suffered damages and an ascertainable loss of money or property in an amount to be determined at trial.

73. Plaintiffs Anastasia Johnston, individually and on behalf of Claire Johnston, Claire Johnston, and Karl Thomsen and members of the Class are entitled to recover statutory penalties, actual, consequential, and punitive damages, equitable and declaratory relief, costs and reasonable attorneys' fees.

COUNT IV
New Hampshire Consumer Protection Act, RSA §§ 358-A *et seq.*
(On Behalf of the New Hampshire Subclass)

74. Plaintiffs repeat and reallege each and every allegation set forth above as if fully set forth herein.

75. The New Hampshire Consumer Protection Act prohibits "any person to use any unfair method of competition or any unfair or deceptive act or practice in the conduct of any trade or commerce within this state." N.H. Rev. Stat. Ann. 358-A:2.

76. Plaintiff Laura Chapin, individually and on behalf of minor Fionn Chapin, and members of the New Hampshire Subclass purchased goods or services primarily for personal, family or household purposes as alleged herein.

77. Defendants engaged in unfair or deceptive acts or practices through the unlawful conduct alleged herein.

78. As a result of Defendants' unfair or deceptive acts or practices alleged herein, Plaintiff Laura Chapin, individually and on behalf of minor Fionn Chapin, and the members of the New Hampshire Subclass have suffered damages and an ascertainable loss of money or property in an amount to be determined at trial.

79. Plaintiff Laura Chapin, individually and on behalf of minor Fionn Chapin, and members of the Class are entitled to recover statutory penalties, actual, consequential, and punitive damages, equitable and declaratory relief, costs and reasonable attorneys' fees.

COUNT V

Connecticut Consumer Protection Act, §§ 42-110 *et seq.*
(On Behalf of the Connecticut Subclass)

80. Plaintiffs repeat and reallege each and every allegation set forth above as if fully set forth herein.

81. The Connecticut Consumer Protection Act prohibits "unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Conn. Gen. Stat. Ann. § 42-110b.

82. Plaintiff Rachel Fernandez, individually and on behalf of minor Hope Moran, and members of the Connecticut Subclass purchased goods or services primarily for personal, family or household purposes as alleged herein.

83. Defendants engaged in unfair, false, misleading, or deceptive acts or practices through the unlawful conduct alleged herein.

84. As a result of Defendants' unfair, false, misleading, or deceptive acts or practices alleged herein, Plaintiff Rachel Fernandez, on behalf of herself and minor Hope Moran, and the members of the Connecticut Subclass have suffered damages and an ascertainable loss of money or property in an amount to be determined at trial.

85. Plaintiff Rachel Fernandez, individually and on behalf of minor Hope Moran, and members of the Class are entitled to recover statutory penalties, actual, consequential, and punitive damages, equitable and declaratory relief, costs and reasonable attorneys' fees.

COUNT VI

Unjust Enrichment, Restitution, and Disgorgement

86. Plaintiffs re-allege and incorporate by reference all prior paragraphs.

87. Defendants' conduct described herein was malicious, willful, reckless, and/or wanton.

88. Defendants' financial benefits resulting from their unlawful and inequitable conduct are economically traceable to their misleading statements regarding the need for double doses of EpiPens and the reason for their two pack-only sales strategy.

89. The Class has conferred Defendants an economic benefit nature of ill-gotten profits resulting from unlawful and inequitable conduct to the Class Members' detriment.

90. Defendants' economic benefit is a direct and proximate result of Defendants' unlawful practices and conduct.

91. It would be inequitable and unjust for Defendants to retain any of the unlawful gains and/or profits resulting from its unlawful and inequitable conduct.

92. Plaintiffs and members of the Class are entitled to recover statutory penalties, actual, consequential, and punitive damages, equitable and declaratory relief, costs and reasonable attorneys' fees.

RELIEF SOUGHT

WHEREFORE, Plaintiffs and the other class members respectfully request that the Court:

a. Certify the Class pursuant to Rule 23 of the Federal Rules of Civil Procedure;

b. Award damages, including compensatory, exemplary, statutory, incidental, consequential, actual, and punitive damages to Plaintiffs and the Class in an amount to be determined at trial;

c. Award Plaintiffs and the Class their expenses and costs of the suit, pre-judgment interest, post-judgment interest, and reasonable attorney's fees;

d. Grant restitution to Plaintiffs and the Class and require Defendants to disgorge their ill-gotten gains;

e. Permanently enjoin Defendants from limiting the sale of EpiPens to two pack EpiPens;

f. Permanently enjoin Defendants from charging unconscionable prices for EpiPens;

g. Grant any and all such other monetary and equitable relief as the Court deems appropriate.

JURY DEMAND

Plaintiffs hereby demand a trial by jury.

Respectfully submitted,

Date: August 23, 2016

THE MILLER LAW FIRM, P.C.

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